



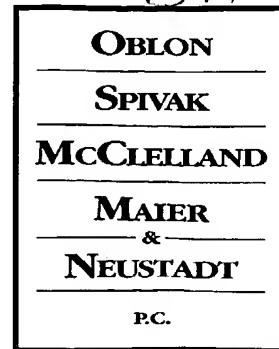
Docket No.: 217926US0PCT

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AUG 30 2004

OFFICE OF PETITIONS

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

RE: Application Serial No.: 10/031,339
Applicants: Paul Alexander JONES, et al.
Filing Date: May 17, 2002
For: NEW USE OF A MACROLIDE COMPOUND
Group Art Unit: 1614
Examiner: Spivack, P. G.

SIR:

Attached hereto for filing are the following papers:

Combined Response and Conditional Petition under 37 C.F.R. 1.181

Our check in the amount of _____ is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

Norman F. Oblon

Harris A. Pitlick

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Customer Number

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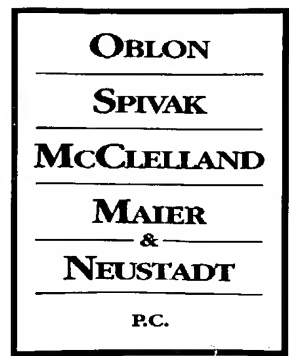
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DOCKET NO: 217926US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

PAUL ALEXANDER JONES, ET AL.

:

: EXAMINER: SPIVACK, P. G.

SERIAL NO: 10/031,339

:

FILED: MAY 17, 2002

: GROUP ART UNIT: 1614

FOR: NEW USE OF A MACROLIDE
COMPOUND

:

COMBINED RESPONSE AND CONDITIONAL PETITION UNDER 37 C.F.R. § 1.181

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

Responsive to the Office communication dated August 9, 2004, Applicants respond as follows:

Statement of Facts

The present application was filed with six claims. Claim 2 reads as follows:

A method for preventing or treating acute or chronic cerebral neurodegenerative diseases, which comprises administering the compound (I) identified in Claim 1 to mammals.

In an Office Action dated September 22, 2003, the Examiner examined all the claims, including Claim 2.

In an Amendment filed March 22, 2004, in response to the Office Action, Applicants canceled all the claims, and introduced new Claims 7-11, all drawn to a method for preventing or treating brain damage caused by ischemia or hemorrhage, which comprises administering said compound (I) to mammals.

In said Office communication, the Examiner finds that newly-submitted Claims 7-11 are directed to an invention that is independent and distinct from the invention originally claimed in that a method for preventing or treating acute or chronic cerebral neurodegenerative diseases is independent and distinct from claims directed to a method for preventing or treating brain damage caused by ischemia or hemorrhage. The Examiner thus holds new Claims 7-11 as directed to a non-elected invention, and thus requires Applicants "to supply the omission or correction in order to avoid abandonment."

Applicants' attorney discussed this matter with the Examiner during an interview held August 13, 2004, in the above-identified application. According to the corresponding Interview Summary, the Examiner maintains her position.

Argument

The specification, in the paragraph bridging pages 5 and 6, describes:

The compound (I) was proved to have a neuroprotective efficacy, though it has no immunosuppressive activity. So, the present invention provides useful neuroprotective agent for preventing or treating acute or chronic cerebral neurodegenerative diseases, **such as** brain damage caused by ischemia or hemorrhage, etc.

(Emphasis added.)

Thus, Applicants have described "brain damage caused by ischemia or hemorrhage" as a species or sub-genus of the genus "acute or chronic cerebral neurodegenerative diseases." Therefore, the Examiner is clearly incorrect in finding that the present claims are drawn to subject matter that is independent and distinct from the subject matter of original Claim 2. Indeed, the Examiner has simply concluded that the respective claims are independent and distinct, without any explanation. This is improper. See *In re Kase*, 71 USPQ2d 1063 (USPTO Director, 2004) (unpublished).

In the Interview Summary, the Examiner's only basis for maintaining her position is that "[n]eurodegenerative diseases, as for example, Alzheimer's disease or Parkinson's disease, are generally not caused by ischemia or hemorrhage."

In reply, whether or not this is true, it is irrelevant. The species or sub-genus method of Claims 7-11 is necessarily narrower than the genus method of Claim 2. That there are methods within the genus but not within the species or sub-genus, while true, does not justify a conclusion that a species or sub-genus is an independent and distinct invention from its genus, sufficient to require the filing of a divisional application for the species or sub-genus method to be examined.

Request for Relief

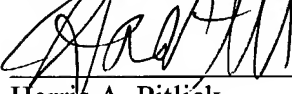
Applicants respectfully request that the Office communication be withdrawn, and that examination resume on Claims 7-11.

Applicants further request that if the Examiner refuses to withdraw the Office communication, this paper be treated as a Petition under 37 C.F.R. § 1.181, the paper **promptly** be transferred to the appropriate PTO Official for deciding such petitions, the Examiner's refusal to withdraw the Office communication be reversed, and the Office communication be vacated.

Respectfully submitted,

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(OSMMN 08/03)

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